2.1 Biocompatibility of Alumina-Ceramic in Total Hip Replacement. Macroscopic- and Microscopic Findings on Capsular Tissues after Long-term Implantation

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Introduction

A very low wear of sliding components for total hip replacement made of alumina-ceramic in self-pairing was proved in simulator investigations (2, 9, 10), being much better than the wear of the conventional metal-PE combination (4–7) and the ceramic-PE combination (38, 39, 42, 49).

Clinically the low wear of self-pairing alumina-ceramic type BIOLOX (Feldmühle/CERASIV) in the self-locking AUTOPHOR and cemented XENOPHOR prosthesis (Osteo AG) was confirmed radiographically after 10 years (29) and recently after 20 years (33) of clinical experience. In laboratory measurements of retrieved prostheses (chiefly after infection or aseptic loosening) the low wear rate of ceramic self-pairing components was also confirmed by *Mittelmeier* et al. (28, 30), being at the socket 5,4 µm and on the head 2,6 µm/year in average. This results were in the range reported by *Boutin* and *Blanquaert* (3) with a wear of 9 µm/year on the head and 6 µm/ year on the socket in average. *Dorlot* (12), found a wear rate of 0,025 µm/year as the normal wear behaviour of firm well positioned alumina ceramic components in self-pairing design, pointing out, that higher wear-rates are caused either by false positioning of the components (primary or secondary due to loosening) or insufficient material properties of the alumina-ceramics. *Dorlot's* (12) results could be confirmed by *Walter's* (41) investigations, reporting wear rates in a range between 0,025 µm/year and 5 µ/year in well positioned cases.

In animal experiences an excellent biocompatibility of the firm and powder alumina-ceramic material was proved (15–20), in opposite to the tissue reactions towards polyethylene wear and PMMA-particles, with aggressive granulomative tissue alterations (25, 27, 43–46). These aggressive reactions of the tissue could be found towards alumina-wear only in a very moderate form related to a local overdose volume in the tissue (1, 8, 36, 40, 45, 48).

From this background the numerous reported excellent clinical results using this biomaterial (21, 22, 31, 32, 34, 35, 37) must be understood as the result of the superior wear behaviour and biocompatibility of the alumina-ceramic sliding parts.

The objective of this study was to investigate the tissue reaction towards alumina-ceramic prosthetic components in human application on a larger number of cases and a longer time of implantation.

Materials and Methods

The macroscopic capsular situation of 134 revision arthroplasties of the hip on 131 patients out of 2667 self-pairing alumina-ceramic prostheses type AUTOPHOR and XENOPHOR implanted in a 20 year period between 1974 and 1993 were analysed. Specimen of capsular tissue were retrieved in all of these cases and investigated histologically. Staining for iron and energy disperse X-ray analysis was performed to specify the wear particles.

With respect to the macroscopic situation at the time of revision surgery the presence of granulomative tissue or debris, the thickness of the joint capsule, their colour and the presence of joint effusion and its aspect were analysed as well as visible wear at the socket and the heads in a semiquantitative assessment. The histological investigations of the retrieved joint capsules consisted of an semiquantitative assessment of the amount of wear particles, an analysis where the particles were stored (macrophages, connective

tissue), the detection of foreign-body giant cells or foreign-body granuloma, the presence of histiocytes especially eosinophyle ones, and an assessment about a necrosis of the synovial-layer and the stratum fibrosum of the joint capsules. The macroscopic and microscopic findings were related to the clinical data of the patients (e.g. survival time of the implants, type of implants, reason for revision surgery).

The cases consisted of 73 male patients with an average age of 53,8 years at the time of revision and 61 female cases with an average age of 55,9 years. In 106 cases it was the first revision and in 28 cases a secondary alloarthroplasty had been already performed.

The average survival time of the implants was 8 years, in 50 cases the survival time of the prosthesis was longer than 7 years. There reason for revision surgery was aseptic loosening in 124 patients and deep infection in 10 cases.

In 112 patients a screwed ceramic socket had **none** been implanted, mostly in combination with a slight self-locking AUTOPHOR-stern and in 21 cases a cemented ceramic socket was used, in all of these cases in combination with a cemented stem.

Results

Intraoperative Macroscopic Findings

In the aseptic cases we found in general no remarkable wear-granulation and only rarely fibrinous wear debris as they are usually found in metal-PE revisions. A stronger thickening of the capsule occurred only in 26% of the aseptic cases and in general no effusion because of joint irritation was found (Table 2.1.1). The tissue showed in 27% a slight and in 12% a moderate grey tinction.

Table 2.1.1 Macroscopic findings

capsule: total (n = 134)		**granulating tissue reaction**	
normal	4%	none	53%
little thickened	24%	little	16%
moderately thickened	37%	moderate	15%
extensive thickened	31%	extensive	16%
capsule: aseptic cases (n = 124)		**joint effusion**	
normal	4%	none	66%
little thickened	27%	little	13%
moderatelty thickened	39%	moderate	13%
extensive thickened	26%	extensive	8%

No visible wear at the sockets was found in 54% of the cases, a slight visible wear was detected in 18%, a moderate wear in 10% and a extensive wear or broken socket was found in either 7%.

51% of the cases showed no visible wear at the head. A slight visible wear of the head was found in 25%, moderate in 9% and extensive in 10%.

Correlating to this in almost all cases no remarkable granulomative destruction of the bone stock could be found (Table 2.1.2).

Table 2.1.2 Macroscopic findings

color of the capsule		**visible wear: Head**	
normal	61%	none	51%
slight gray tinction	27%	slight	25%
remarkable gray tinction	12%	moderate	9%
		extensive	10%
visible wear: Socket		**destruction of the bone stock**	
none	54%	none	22%
slight	18%	little	37%
moderate	10%	moderate	24%
extensive	7%	extensive	17%
broken	7%		

Microscopic Evaluation

The size of wear particles was in general very small, varying between 0,5 and 2 μm. The amount of wear particles was none or minimal in 50% of the cases, moderate in 39% and only in 11% an extensive amount of wear particles was found.

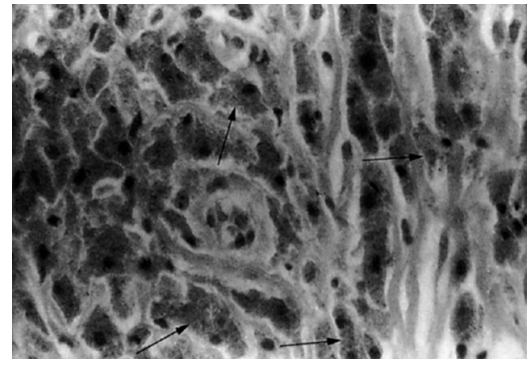

Fig. 2.1.1 Microscopic aspect of capsular tissue: Macrophages with stored alumina-ceramic wear particles (arrows); the cells are enlarged but alive; no wear particles in the connective tissue (hematoxyline/eosine-staining; manification 400 times)

Table 2.1.3 Microscopic findings

amount of wear particles	
absent	14%
little	36%
moderate	39%
extensive	11%
storage of the wear particles	
within macrophages	82%
free in connective tissue	10%
mixed	7%
amount of macrophages (n = 116)	
little	66%
moderate	24%
extensive	10%
foreign-body giant cells	18%
sporadic	11%
aseptic cases (n = 124)	4%
septic cases (n = 10)	50%
larger amount	7%
aseptic cases (n = 124)	3%
septic cases (n = 10)	50%
foreign-body granuloma	6%
aseptic cases (n = 124)	4%
septic cases (n = 10)	33%

The position of wear particles was within macrophages in 82% of the cases (Fig. 2.1.1), in 10% free in the connective tissue and in 7% mixed. The prevailing position of the wear particles within macrophages shows a particle collection and the position of the macrophages around the lymphatic vessels an obvious clearance activity.

Foreign-body giant cells were detected sporadically in only 18% of the cases and granulating foreign-body reaction only in 6%, mainly in septic cases and cases with cemented ceramic parts and PMMA-particles (Table 2.1.3).

A hyperplasia of the synovial layer was found in a moderate or extensive wax only in 23% of the cases. In 77% a normal or only slightly thickened synovia was found. The thickness of the stratum fibrosum was also normal or slightly thicker in 75% of the cases. A necrosis of parts of the superficial synovial layer was detectable in only 7% of the cases and necroses in the stratum fibrosum of the capsule were seen in not a single case.

In cases of bacterial infection the histological image was superposed by inflammatory cell reaction (with granulocytes and lymphocytes) without relation to the wear particles (Table 2.1.4). The further analysis of our findings showed a correlation of the amount of wear particles to the survival time of the implants with a decreased number of cases where only a little amount of wear particles could be detected and an increase of those cases with a moderate amount of wear the longer the implantation time was. The irregularity in the cases with an extensive wear reflects that these are chiefly cases with uncommon conditions such as material failure or loosened and tilted sockets (Fig. 2.1.2).

A positive correlation could be found between the occurrence of foreign-body giant cells and the type of prosthesis (cemented), septic cases, as well as towards a longer survival time of the prostheses. From this it can be assumed that an irritation of the tissue with foreign-body reaction is caused by cement-particles, infection and a longer lasting influence of a larger amount of ceramic wear particles.

Table 2.1.4 Microscopic findings

thickness of the synovial layer	
normal	44%
little thickened	33%
moderately thickened	16%
extensive thickened	7%
necrosis	7%
thickness of the stratum fibrosum	
normal	20%
little thickened	55%
moderately thickened	16%
extensively thickened	7%
necrosis	0%
calcification/ ossification	42%
inflammatory cell reaction	
by granuloyctes (septic cases)	6%
by lymphozytes (18% aseptic)	25%

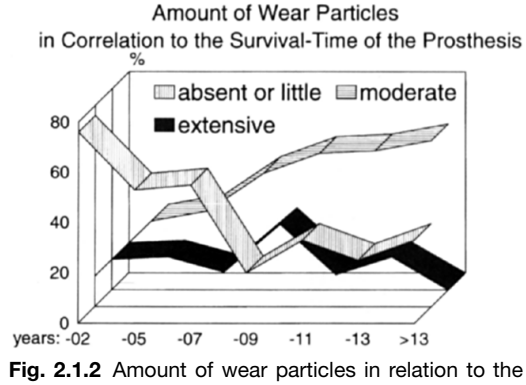

Fig. 2.1.2 Amount of wear particles in relation to the survival time of the prosthesis

Discussion

With the presented study the excellent biocompatibility of sliding components for total hip replacement made of alumina-ceramic (BIOLOX) shown in earlier investigations (14–20) could be confirmed. Despite of the fact, that a negative selection of cases needing revision arthroplasty of the hip was investigated. This circumstance was already pointed out by *Christel* (8). However, in opposite to *Harms* and *Mäusle* (16, 17, 19) who could not find any foreign-body cell reaction, in the presented investigation foreign-body giant cells were detectable in a small percentage of cases. The main reason for this discrepancy might be the small number of cases with a short evaluation-time in the material presented by the cited authors. In concordance to the presented results other investigators showed that even using the highly inert alumina-ceramic. foreign- body reaction towards the wear particles can occur (1, 85 245 36, 40, 45, 49). The conclusion of these authors, that a large amount of wear particles overstressing the clearance capacity of the tissue can be the reason for this tissue reaction could be confirmed by the analysis of our findings.

In cemented cases a foreign-body cell reaction could be found as answer to the bone cement particle. This relation of the foreign-body cells toward the bone cement particles in cases of cemented ceramic components was shown already by *Willert* et al. (43) and *Christel* (8).

Despite of the fact that there was a small foreign-body cell reaction detectable, chiefly as an answer to bone cement particles, or the irritation through infection, we could not find neither in our analysis of the macroscopic situation nor histologically any indication that the ceramic wear plays a role in the pathogenesis of aseptic loosening as it is shown for the wear particles of ultra-high molecular weight polyethylene by *Willert* et al. (46). This pathogenesis of aseptic loosening in prostheses with polyethylene components through granulomative tissue could be confirmed by *Fornasier* et al. (13) and *Korovessis* and *Repanti* (23) who found aggressive foreign-body granulations even at the cement-bone interface of firm conventional cemented endoprostheses (Fig. 2.1.3).

Especially *Fornasier* et al. (13) pointed out that there is a particle transportation of polyethylene wear particles in the membrane between cement and bone in firm endoprostheses with similar histological aspect as in the capsule of loose cemented endoprostheses, playing an important role in the in initiating of aseptic loosening. In opposite to the findings in cemented prostheses or cases with the couple polyethylene/metal we found nearly no tissue necroses and only a slight fibrosis of the tissue in the analysed cases with alumina-ceramic parts in self-pairing. To our opinion this is another sign for the biocompatibility of the used ceramic implants and the alumina wear particles, a result that is confirmed by *Christel* (8).

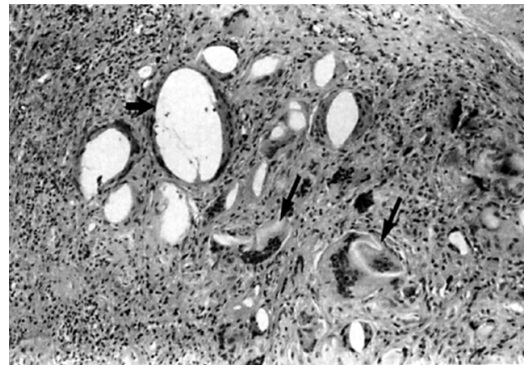

Fig. 2.1.3 Microscopic aspect of capsular tissue after total hip replacement with the conventional metal/PE couple: foreign-body giant cells and foreign-body granuloma surrounding PE- wear particles and PMMA-particles dominate the microscopic appearance of the capsule (hematoxyline/eosine-staining; manification 200 times)

Our result that ceramic wear does not lead to destruction of the bone stock can also be proved by the analysis of the used revision implants. Only 10 out of 79 cases with loosened socket (12%) needed a Burch-Schneider-shell for acetabular reconstruction, in 71% of the bone stock was good enough to replace the loosened socket by a cementless one, in general only one size bigger than the former implant.

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